

109TH CONGRESS
1ST SESSION

H. R. 1822

To prohibit human cloning and protect stem cell research.

IN THE HOUSE OF REPRESENTATIVES

APRIL 26, 2005

Mrs. BONO (for herself, Ms. DEGETTE, Mr. CASTLE, Mr. MARKEY, and Mr. BASS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To prohibit human cloning and protect stem cell research.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Human Cloning Ban
5 and Stem Cell Research Protection Act of 2005”.

6 **SEC. 2. PURPOSES.**

7 It is the purpose of this Act to prohibit human
8 cloning and to protect important areas of medical re-
9 search, including stem cell research.

**TITLE I—PROHIBITION ON
HUMAN CLONING**

SEC. 101. PROHIBITION ON HUMAN CLONING.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended by adding at the end the following:

**“CHAPTER X—PROHIBITION ON HUMAN
CLONING**

“SEC. 1001. PROHIBITION ON HUMAN CLONING.

“(a) DEFINITIONS.—In this section:

“(1) HUMAN CLONING.—The term ‘human cloning’ means implanting or attempting to implant the product of nuclear transplantation into a uterus or the functional equivalent of a uterus.

“(2) HUMAN SOMATIC CELL.—The term ‘human somatic cell’ means any human cell other than a haploid germ cell.

“(3) NUCLEAR TRANSPLANTATION.—The term ‘nuclear transplantation’ means transferring the nucleus of a human somatic cell into an oocyte from which the nucleus or all chromosomes have been or will be removed or rendered inert.

“(4) NUCLEUS.—The term ‘nucleus’ means the cell structure that houses the chromosomes.

1 “(5) OOCYTE.—The term ‘oocyte’ means the fe-
2 male germ cell, the egg.

3 “(6) UNFERTILIZED BLASTOCYST.—The term
4 ‘unfertilized blastocyst’ means an intact cellular
5 structure that is the product of nuclear transplan-
6 tation. Such term shall not be construed to include
7 any biological product derived from an intact cellular
8 structure that is the product of nuclear transplan-
9 tation, including stem cells, other cells, and cellular
10 structures.

11 “(b) PROHIBITIONS ON HUMAN CLONING.—It shall
12 be unlawful for any person or other legal entity, public
13 or private—

14 “(1) to conduct or attempt to conduct human
15 cloning;

16 “(2) to ship the product of nuclear transplan-
17 tation in interstate or foreign commerce for the pur-
18 pose of human cloning in the United States or else-
19 where; or

20 “(3) to export to a foreign country an
21 unfertilized blastocyst if such country does not pro-
22 hibit human cloning.

23 “(c) PROTECTION OF RESEARCH.—Nothing in this
24 section shall be construed to restrict practices not ex-
25 pressly prohibited in this section.

1 “(d) RIGHT OF ACTION.—Nothing in this section
2 shall be construed to give any individual or person a pri-
3 vate right of action.”.

4 (b) PROHIBITED ACTS.—

5 (1) IN GENERAL.—Section 301 of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is
7 amended by adding at the end the following:

8 “(hh) The violation of paragraph (1), (2), or (3) of
9 section 1001(b) (relating to human cloning).”.

10 (2) CRIMINAL PENALTIES.—Section 303(b) of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 333(b)) is amended by adding at the end the
13 following:

14 “(7) Notwithstanding subsection (a), any per-
15 son who violates section 301(hh) shall be imprisoned
16 not more than 10 years and fined in accordance with
17 title 18, United States Code, or both.”.

18 (3) CIVIL PENALTIES.—Section 303 of the Fed-
19 eral Food, Drug, and Cosmetic Act (21 U.S.C. 333)
20 is amended by adding at the end:

21 “(g)(1) Any person who violates section 301(hh) shall
22 be liable to the United States for a civil penalty in an
23 amount not to exceed the greater of—

24 “(A) \$10,000,000; or

1 “(B) an amount equal to three times the
2 amount of the gross pecuniary gain resulting from
3 the violation.

4 “(2) Paragraphs (3) through (5) of subsection (f)
5 apply with respect to a civil penalty under this subsection
6 to the same extent and in the same manner as such para-
7 graphs (3) through (5) apply with respect to a civil penalty
8 under subsection (f).”.

9 (4) FORFEITURE.—Section 303 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 333), as
11 amended by paragraph (3), is amended by adding at
12 the end the following:

13 “(h) Any property, real or personal, derived from or
14 used to commit a violation or attempted violation of sec-
15 tion 301(hh), or any property traceable to such property,
16 shall be subject to forfeiture to the United States in ac-
17 cordance with the procedures set forth in chapter 46 of
18 title 18, United States Code.”.

19 **SEC. 102. OVERSIGHT REPORTS ON ACTIONS TO ENFORCE**
20 **CERTAIN PROHIBITIONS.**

21 (a) REPORT ON ACTIONS BY SECRETARY OF HHS
22 TO ENFORCE PROHIBITION ON HUMAN CLONING.—Not
23 later than 1 year after the date of the enactment of this
24 Act, the Secretary of Health and Human Services shall
25 prepare and submit to the Committee on the Judiciary of

1 the Senate and the Committee on Energy and Commerce
2 of the House of Representatives a report that—

3 (1) describes the actions taken by the Secretary
4 to enforce the provisions of chapter X of the Federal
5 Food, Drug, and Cosmetic Act (as added by section
6 101);

7 (2) describes the personnel and resources the
8 Secretary has utilized to enforce the provisions of
9 such chapter; and

10 (3) contains a list of violations, if any, of the
11 provisions of such chapter.

12 (b) REPORT ON COORDINATION OF ENFORCEMENT
13 ACTIONS AMONG FEDERAL, STATE, AND LOCAL GOVERN-
14 MENTS WITH RESPECT TO HUMAN CLONING.—

15 (1) REPORT.—Not later than 1 year after the
16 date of the enactment of this Act, the Secretary of
17 Health and Human Services shall prepare and sub-
18 mit to the Committee on the Judiciary of the Senate
19 and the Committee on Energy and Commerce of the
20 House of Representatives a report that—

21 (A) describes how the Secretary coordi-
22 nates the enforcement of violations of section
23 301(hh) of the Federal Food, Drug, and Cos-
24 metic Act (as added by section 101) with en-
25 forcement actions taken by State or local gov-

1 ernment law enforcement officials with respect
2 to similar State laws relating to human cloning;
3 and

4 (B) describes the status and disposition
5 of—

- 6 (i) Federal appellate litigation with re-
7 spect to such section 301(hh) and State
8 appellate litigation with respect to similar
9 State laws relating to human cloning; and
10 (ii) civil litigation, including actions to
11 appoint guardians, related to human
12 cloning.

13 (2) DEFINITION.—In this subsection, the term
14 “similar State law relating to human cloning” means
15 a State or local law that provides for the imposition
16 of criminal penalties on individuals who are deter-
17 mined to be conducting or attempting to conduct
18 human cloning (as defined in section 1001 of the
19 Federal Food, Drug, and Cosmetic Act (as added by
20 section 101)).

21 (c) REPORT ON INTERNATIONAL LAWS RELATING TO
22 HUMAN CLONING.—Not later than 1 year after the date
23 of the enactment of this Act, the Secretary of Health and
24 Human Services shall prepare and submit to the Congress
25 a report that—

1 (1) describes the laws adopted by foreign coun-
 2 tries related to human cloning;

3 (2) describes the actions taken by the chief law
 4 enforcement officer in each foreign country that has
 5 enacted a law described in paragraph (1) to enforce
 6 such law; and

7 (3) describes the multilateral efforts of the
 8 United Nations and elsewhere to ban human cloning.

9 **TITLE II—ETHICAL REQUIRE-**
 10 **MENTS FOR NUCLEAR TRANS-**
 11 **PLANTATION RESEARCH**

12 **SEC. 201. ETHICAL REQUIREMENTS FOR NUCLEAR TRANS-**
 13 **PLANTATION RESEARCH.**

14 Title IV of the Public Health Service Act (42 U.S.C.
 15 281 et seq.) is amended by adding at the end the fol-
 16 lowing:

17 **“PART J—ETHICAL REQUIREMENTS FOR**
 18 **NUCLEAR TRANSPLANTATION RESEARCH**

19 **“SEC. 499A. ETHICAL REQUIREMENTS FOR NUCLEAR**
 20 **TRANSPLANTATION RESEARCH, INCLUDING**
 21 **INFORMED CONSENT, INSTITUTIONAL RE-**
 22 **VIEW BOARD REVIEW, AND PROTECTION FOR**
 23 **SAFETY AND PRIVACY.**

24 **“(a) DEFINITIONS.—**

1 “(1) IN GENERAL.—The definitions contained
2 in section 1001(a) of the Federal Food, Drug, and
3 Cosmetic Act shall apply for purposes of this section.

4 “(2) OTHER DEFINITIONS.—In this section:

5 “(A) DONATING.—The term ‘donating’
6 means giving without receiving valuable consid-
7 eration.

8 “(B) FERTILIZATION.—The term ‘fertiliza-
9 tion’ means the fusion of an oocyte containing
10 a haploid nucleus with a male gamete (sperm
11 cell).

12 “(C) VALUABLE CONSIDERATION.—The
13 term ‘valuable consideration’ does not include
14 reasonable payments—

15 “(i) associated with the transpor-
16 tation, processing, preservation, or storage
17 of a human oocyte or of the product of nu-
18 clear transplantation research; or

19 “(ii) to compensate a donor of one or
20 more human oocytes for the time or incon-
21 venience associated with such donation.

22 “(b) APPLICABILITY OF FEDERAL ETHICAL STAND-
23 ARDS TO NUCLEAR TRANSPLANTATION RESEARCH.—Re-
24 search involving nuclear transplantation shall be con-
25 ducted in accordance with subpart A of part 46 of title

1 45, or parts 50 and 56 of title 21, Code of Federal Regula-
2 tions (as in effect on the date of the enactment of the
3 Human Cloning Ban and Stem Cell Research Protection
4 Act of 2005), as applicable.

5 “(c) PROHIBITION ON CONDUCTING NUCLEAR
6 TRANSPLANTATION ON FERTILIZED EGGS.—A somatic
7 cell nucleus shall not be transplanted into a human oocyte
8 that has undergone or will undergo fertilization.

9 “(d) FOURTEEN-DAY RULE.—An unfertilized blasto-
10 cyst shall not be maintained more than 14 days from its
11 first cell division, not counting any time during which it
12 is stored at temperatures less than zero degrees centi-
13 grade.

14 “(e) VOLUNTARY DONATION OF OOCYTES.—

15 “(1) INFORMED CONSENT.—In accordance with
16 subsection (b), an oocyte may not be used in nuclear
17 transplantation research unless such oocyte shall
18 have been donated voluntarily by and with the in-
19 formed consent of the woman donating the oocyte.

20 “(2) PROHIBITION ON PURCHASE OR SALE.—
21 No human oocyte or unfertilized blastocyst may be
22 acquired, received, or otherwise transferred for valu-
23 able consideration if the transfer affects interstate
24 commerce.

1 “(f) SEPARATION OF IN VITRO FERTILIZATION LAB-
2 ORATORIES FROM LOCATIONS AT WHICH NUCLEAR
3 TRANSPLANTATION IS CONDUCTED.—Nuclear transplan-
4 tation may not be conducted in the same laboratory or
5 other physical facility in which human oocytes are subject
6 to assisted reproductive technology treatments or proce-
7 dures.

8 “(g) CIVIL PENALTIES.—Whoever intentionally vio-
9 lates any provision of subsections (b) through (f) shall be
10 subject to a civil penalty in an amount that is appropriate
11 for the violation involved, but not more than \$250,000.”.

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